



INSTRUCTIONS

OLYMPUS

EndoTherapy

DISPOSABLE BALLOON CATHETER

B5-2C/2Q/2LA

B7-2C/2Q/2LA

USA: CAUTION:

- **This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**
- Federal law restricts this device to sale by or on the order of a physician.

CE 0197

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Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:



Refer to instructions.



Single use only



Use by (expiration date)



Sterilized using ethylene oxide



Sterilization lot number



Lot number



Compatible with a $\varnothing 0.53$ mm (0.021 inch) guidewire.



Compatible with a $\varnothing 0.89$ mm (0.035 inch) guidewire.



Manufacturer



Authorised representative in the European Community

Important Information — Please Read Before Use

Intended Use

○ B5-2C, B7-2C

These instruments have been designed to be used with Olympus endoscopes to inject contrast medium or other medical fluid into the bile duct, pancreatic duct, and respiratory organs. They can also be used for irrigation, hemostasis within the respiratory organs, and retrieval of foreign bodies within the bile duct, pancreatic duct and respiratory organs. Do not use these instruments for any purpose other than their intended use.

○ B5-2Q/2LA, B7-2Q/2LA

These instruments have been designed to be used with Olympus endoscopes to inject contrast media into the biliary or pancreatic tract. They can also be used for retrieval of biliary or pancreatic stones. Do not use these instruments for any purpose other than their intended use.

Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.

Keep this and all related instruction manuals in a safe, accessible location.

If you have any questions or comments about any information in this manual, please contact Olympus.

User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument Compatibility

Refer to the Tables in Section 2.2, “Specifications” to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury or equipment damage.

Storage

This instrument was shipped in a sterile condition. Store it following the instructions in Chapter 3, “Storage”. Improper storage can present an infection control risk, cause equipment damage or reduce performance. This instrument is a single-use, disposable item that is not to be reprocessed. Do not reuse or attempt to sterilize.

Repair and Modification

This instrument contains no user-serviceable parts. Do not disassemble, modify or attempt to repair; patient or user injury and equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

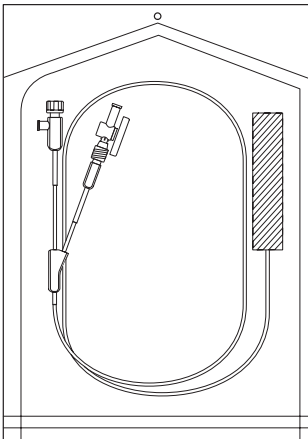
Natural Rubber Latex Medical Alert

This product contains natural rubber latex which may cause allergic reactions. The balloon at the distal end of the insertion portion is made of natural rubber latex. Do not use this product on a latex-sensitive patient.

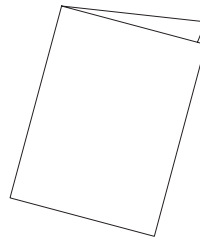
Chapter 1 Checking the Package Contents

1.1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing, or you have any questions, do not use the instrument; immediately contact Olympus.



**Balloon Catheter
(Sterile, Single use only)**

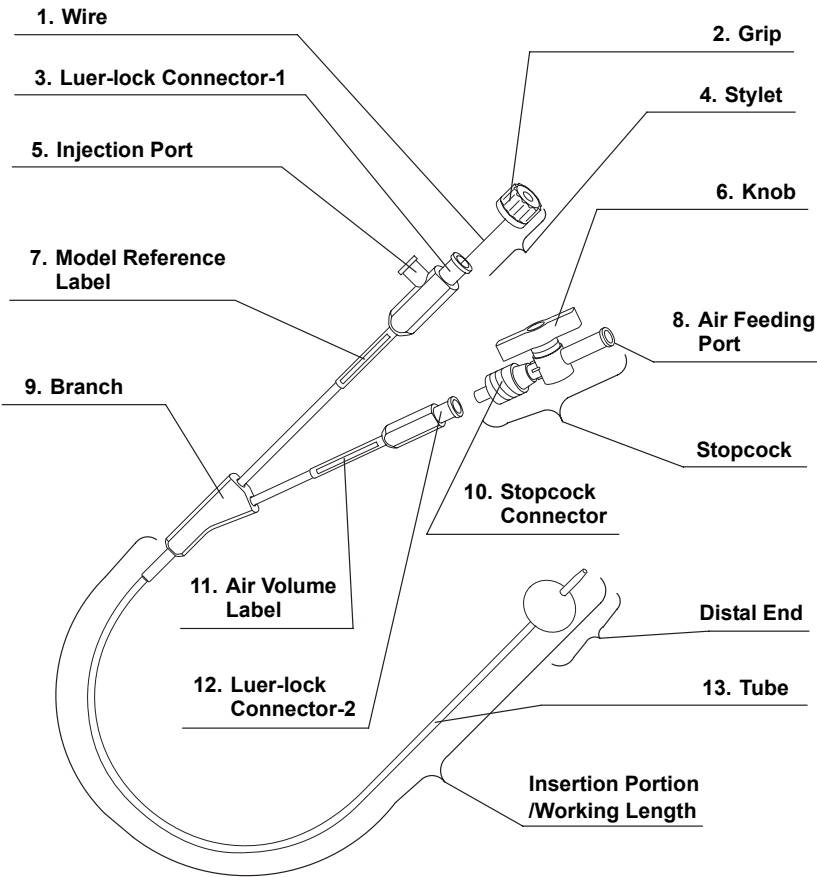


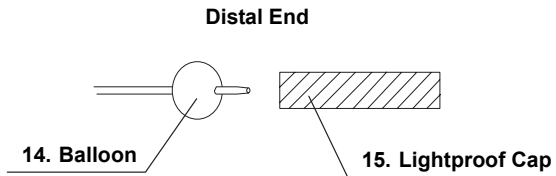
Instruction Manual

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature and Functions

The sterile instrument is sealed in a package.





1. Wire

The wire is available with the B7-2C/2Q/2LA only.
Inserted in the tube to prevent the tube from kinking.

2. Grip

The grip is attached to Luer-lock connector-1.

3. Luer-lock Connector-1

The Luer-lock is attached to the grip.

4. Stylet

The stylet is available with the B7-2C/2Q/2LA only
and incorporates the grip and wire.

5. Injection Port

Attach a syringe the injection port to inject contrast
medium, medical fluid or saline.

6. Knob

The knob switches a valve to control the airflow.
When the valve is opened, the balloon can be
inflated. After inflation, the knob is rotated and the
valve is shut, maintaining inflation.

7. Model Reference Label

The model reference label indicates the product
number.

8. Air Feeding Port

A syringe is mounted on the air feeding port, and air is injected into the balloon to inflate it.

9. Branch

The color of the branch indicates the minimum instrument channel diameter required for the endoscope to be compatible.

10. Stopcock Connector

The stopcock connector is attached to Luer-lock connector-2 to secure the stopcock.

11. Air Volume Label

Indicates the air volume required for maximum balloon inflation.

12. Luer-lock Connector-2

The Luer-lock connector is attached to the stopcock connector.

13. Tube

The tube works as the channel through which air is fed into the balloon from the air feeding port and as the channel through which contrast medium, medical fluid or saline is injected.

14. Balloon

The balloon can be inflated and deflated using the syringe attached to the air feeding port.

15. Lightproof Cap

The lightproof cap prevents the latex rubber balloon from deteriorating when transported or stored.

2.2 Specifications

The compatible Olympus endoscopes are listed in the table on the following page. New endoscopes released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

WARNING

Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction or equipment damage may result.

Operating Environment

Ambient Temperature	10 to 40°C (50 to 104°F)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060 hPa (0.71 to 1.08 kgf/cm ²) (10.1 to 15.4 psia)

Specifications

WARNING

The volume of the air in the balloon should not exceed the parameters specified in the following tables. Otherwise, the balloon may burst or may not deflate. When the balloon does not deflate, do not operate the balloon catheter with excessive force. Otherwise, the distal end of the instrument may break off and could remain inside the patient.

Model	B5-2C	B7-2C
Shape of the Balloon		
Maximum Insertion Portion Diameter (mm)	ø 1.95	ø 2.55
Working Length (mm)	1050	
Diameter after inflation (mm)	ø 11.0	ø 13.0
Maximum Air Volume (ml (cc))	1.5	1.7
Compatible Guide Wire (mm (inch))	ø 0.53 (0.021)	ø 0.89 (0.035)

Compatible Olympus Endoscopes (All of these parameters should be met.)	Length and Model	Working length less than 600 mm; CHF, BF	
	Channel	ø 2, ø 2.2	ø 2.8, ø 3.2
	Inner	(Blue);	(Yellow)
	Diameter (mm)	ø 2.6	
	(Color Code)	(Green); ø 2.8, ø 3.2 (Yellow)	

NOTE

The G35-2LB and G35-2LD guidewires are available from Olympus for use in combination with the B7-2C.

Medical Device Directive		This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
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Model	B5-2Q	B7-2Q
Shape of the Balloon		
Maximum Insertion Portion Diameter (mm)	ø 1.95	ø 2.55
Working Length (mm)	1950	
Diameter after inflation (mm)	ø 11.0	ø 13.0

Maximum Air Volume (ml (cc))		1.6	1.8
Compatible Guide Wire (mm (inch))		ø 0.53 (0.021)	ø 0.89 (0.035)
Compatible Olympus Endoscopes	Length and Model	Working length less than 1400 mm; JF, TJF	
(All of these parameters should be met.)	Channel	ø 2.2	ø 2.8, ø 3.2
	Inner Diameter (mm)	(Blue); ø 2.8, ø 3.2 (Yellow);	(Yellow); ø 3.7, ø 4.2 (Orange);
	(Color Code)	ø 3.7, ø 4.2 (Orange); ø 5.5 (Pink)	ø 5.5 (Pink)

NOTE

The G35-2LB and G35-2LD guidewires are available from Olympus for use in combination with the B7-2Q.

Model	B5-2LA	B7-2LA
Shape of the Balloon		
Maximum Insertion Portion Diameter (mm)	ø 1.95	ø 2.55
Working Length (mm)	3500	
Diameter after inflation (mm)	ø 11.0	ø 13.0

Maximum Air Volume (ml (cc))			
		1.8	2.0
Compatible Guide Wire (mm (inch))			
		ø 0.53 (0.021)	ø 0.89 (0.035)
Compatible Olympus Endoscopes (All of these parameters should be met.)	Length and Model	Working length less than 1400 mm; JF, TJF	
	Channel	ø 2.2	ø 2.8, ø 3.2
	Inner Diameter (mm)	(Blue); ø 2.8, ø 3.2 (Yellow);	(Yellow); ø 3.7, ø 4.2 (Orange);
	(Color Code)	ø 3.7, ø 4.2 (Orange); ø 5.5 (Pink)	ø 5.5 (Pink)

NOTE

The G35-2LB and G35-2LD guidewires are available from Olympus for use in combination with the B7-2LA.

Medical Device Directive



This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I

Chapter 3 Storage

WARNING

- Do not store the instrument in a sterile package that is damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.
- Do not store the sterile package containing the instrument in place where it will be damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

3.1 Inspection Before Storage

Prior to storage, inspect the sterile package as follows:

Confirm that the sterile package containing the instrument is free from tears, inadequate sealing or water damage. If tears, inadequate sealing, or water damage is detected, do not use the instrument; contact Olympus.

3.2 Storage

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight. Ensure that the package is not crushed by surrounding objects during storage.

Chapter 4 *Preparation, Inspection and Operation*

The instrument was shipped in a sterile condition.

WARNING

- This product contains natural rubber latex which may cause allergic reactions. The balloon at the distal end of the insertion section is made of natural rubber latex. Do not use this product on a latex-sensitive patient.
- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before each case, prepare and inspect the instrument as instructed below. Inspect other equipment to be used with the instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use the instrument; contact Olympus. Damage or irregularity may compromise patient or user safety, such as an infection control risk, tissue irritation, punctures, hemorrhages or mucous membrane damage and may result in more-severe equipment damage.

CAUTION

Do not coil the insertion portion with a diameter of less than 15 cm. This could damage the insertion portion.

4.1 Preparation

Equipment and Personal Protective Equipment

Prepare all equipment and personal protective equipment that will be used with the instrument in accordance with their respective instruction manuals. Appropriate personal protective equipment may include: eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.

Spare Instrument

Always have a spare instrument available.

Sterile Syringe, Contrast Medium, Medical Fluid , or Saline for Inspection

Prepare a sterile syringe and contrast medium, and medical fluid or saline solution for inspection.

4.2 Inspection

Wear the personal protective equipment as specified above.

Before each case, always inspect the instrument according to the following procedures.
If an abnormality in the instrument is detected, use a spare instrument, inspecting it thoroughly before use.

Inspection of the Sterile Package

Inspect the sterile package for tears, inadequate sealing, or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Use a spare instead.

Appearance Inspection

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

1. Remove the lightproof cap from the distal end of the instrument.
2. Gently run your fingertips over the entire length of the insertion portion to check for any crushed areas, excessive bends, broken areas or other damages.
3. Confirm that the distal end of the instrument appears exactly as shown in the tables in Section 2.2, "Specifications" and is not damaged.

Making and Inspecting the Connections

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

1. When using the B5-2C/2Q/2LA, push the grip into Luer-lock connector-1. Confirm that the grip is securely attached to Luer-lock connector-1.
2. When using the B7-2C/2Q/2LA, insert the wire of the stylet through Luer-lock connector-1 into the tube. Mount the grip onto Luer-lock connector-1. Make sure the stylet is securely attached.
3. Screw the stopcock connector into Luer-lock connector-2. Make sure the stopcock is securely attached.

4. Confirm that the branch and Luer-lock connectors are free from disconnection or looseness.

Inspection of Operation

CAUTION

- The volume of air in the balloon should not exceed the parameters specified in the tables in Section 2.2, “Specifications”. Otherwise, the balloon may burst.
- Do not inflate the balloon rapidly. Otherwise, the balloon may burst.
- Inflate the balloon with air only. Inflation with anything other than air may hinder expansion and contraction of the balloon.

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

1. Confirm that the stopcock knob is positioned as shown in Figure 4.1.

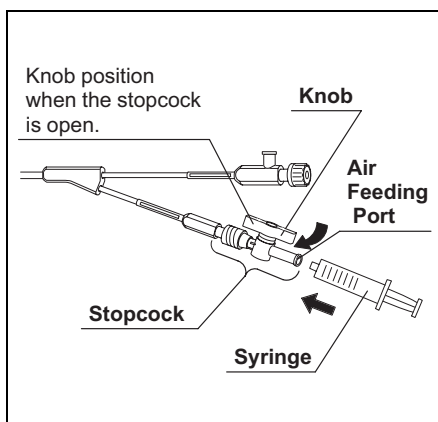


Figure 4.1

2. Connect the sterile syringe onto the air feeding port (see Figure 4.1).

3. While referring to the tables in Section 2.2, “Specifications”, slowly inflate the balloon to the desired size. Confirm that the balloon inflates.
4. With the balloon inflated, turn the knob on the stopcock 90° to close the stopcock.
5. Confirm that the balloon does not contract.
6. Turn the knob on the stopcock back 90° to open the stopcock.
7. Pull the sterile syringe’s plunger to deflate the balloon.
8. Remove the grip from Luer-lock connector-1.
9. When using the B7-2C/2Q/2LA, withdraw the stylet from the tube.
10. Insert the guidewire into the opening at the distal end of the tube. Confirm that the guidewire pokes smoothly and sufficiently out of Luer-lock connector-1.

Inspecting Irrigation

Do not use the instrument if the contrast medium, medical fluid or saline solution cannot be injected or if it leaks from any area other than the distal end. In this case, use a spare instead.

WARNING

Use a contrast medium, medical fluid or saline solution intended for patient use when inspecting irrigation. Other fluids may remain inside the channel and could pose an infection control risk or cause tissue irritation.

1. When using the B5-2C/2Q/2LA, push the grip into Luer-lock connector-1. Confirm that the grip is securely attached to Luer-lock connector-1.
2. When using the B7-2C/2Q/2LA, insert the stylet wire into the tube through Luer-lock connector-1. Then mount the grip onto Luer-lock connector-1 and confirm that the stylet is securely attached.
3. Inject contrast medium, medical fluid or saline into the instrument's injection port using a sterile syringe. Confirm that the fluid comes out of the distal end (see Figure 4.2).

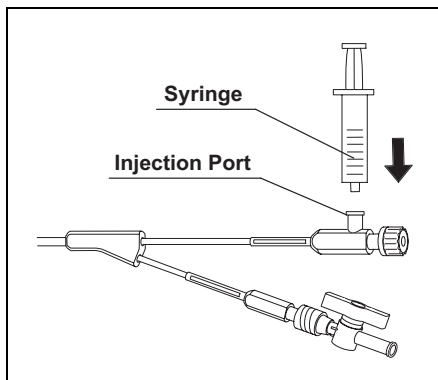


Figure 4.2

4. Make sure that the contrast medium, medical fluid or saline does not leak from any area other than the distal end of the instrument.
5. Connect another syringe containing air to the instrument's injection port. Inject air into the insertion portion to discharge the contrast medium, medical fluid or saline solution.

4.3 Operation

The operator of the instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infectious material from the patient could pose an infection control risk. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- Do not use the balloon catheter to retrieve a calculus which is larger than the fistula or lumen size. Doing so could cause patient injury such as hemorrhages or mucous membrane damage. It could also burst the balloon or cause the balloon to become stuck in the fistula or lumen, resulting that the distal end of the instrument breaks off and remains inside the fistula or lumen.

- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view or in the X-ray images, do not use it. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not angulate the bending section of the endoscope (or operate the forceps elevator if applicable) abruptly while the distal end of the insertion portion is extended from the distal end of the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not force the distal end of the insertion portion against body cavity tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- The volume of the air in the balloon should not exceed the parameters specified in the tables in Section 2.2, “Specifications”. Otherwise, the balloon may burst or may not deflate properly. When the balloon does not deflate, do not operate the balloon catheter with excessive force. Otherwise, the distal end of the instrument may break off and could remain inside the patient.
- Do not inflate the balloon rapidly. The balloon may burst and mucous membrane damage can result.

- Inflate the balloon with air only. Inflation with anything other than air may hinder contraction of the balloon and make impossible to withdraw the instrument from the body cavity.
- When using the B7-2C/2Q/2LA, do not withdraw the stylet from the tube quickly. Infectious substances attached to the stylet such as the patient's blood and mucous may scatter, posing an infection control risk.
- When using the B7-2C/2Q/2LA, be careful when handling the distal end of the removed stylet. The stylet has a very sharp tip and accidental punctures may pose an infection control risk or cause tissue irritation.

Inserting Into the Endoscope

WARNING

- Confirm that the balloon is completely deflated when inserting the instrument into the endoscope. If the balloon is inflated, the distal end of the instrument may extend from the distal end of the endoscope abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- When using a guidewire, hold the guidewire when inserting the instrument. Otherwise, it will move with the instrument. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

- Do not force the instrument if resistance to insertion is encountered. Reduce the angulation (or lower the forceps elevator if applicable) until the instrument passes smoothly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not advance or extend the instrument abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.

CAUTION

- When inserting the instrument into the endoscope, hold it close to the biopsy valve and keep it as straight as possible relative to the biopsy valve. Otherwise, the insertion portion could be damaged.
- Insert the instrument slowly. Abrupt insertion could damage the endoscope and/or instrument.

○ Using the B5-2C, B7-2C

1. Carefully insert the instrument into the biopsy valve or T-plug (see Figure 4.3).

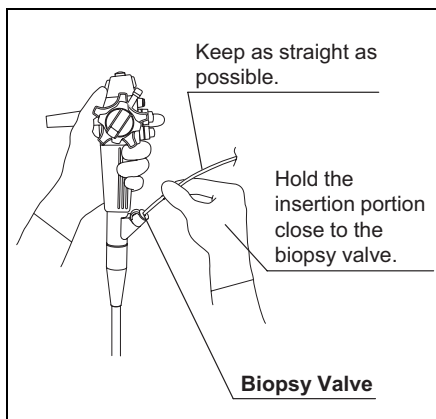


Figure 4.3

2. Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.

○ Using the B5-2Q/2LA, B7-2Q/2LA

WARNING

When using the B5-2Q/2LA or B7-2Q/2LA, raise the forceps elevator to its maximum height. If the forceps elevator is down, you will not be able to see the distal end of the insertion portion in the endoscopic field of view. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

1. Raise the forceps elevator to its maximum height.
2. Carefully insert the instrument into the biopsy valve (see Figure 4.3).

3. When using a guidewire, hold the guidewire in position and insert the instrument into the endoscope along the guidewire.
4. When the distal end of the insertion portion contacts the forceps elevator, lower the forceps elevator.
5. Advance the instrument another 20 mm and raise the forceps elevator. The distal end of the instrument will be visible in the endoscopic field of view.

Applications

○ Radiography, Injecting medical fluid, and Irrigation

1. When using the B5-2C/2Q/2LA, push the grip into Luer-lock connector-1. Confirm that the grip is securely attached to Luer-lock connector-1.
2. When using the B7-2C/2Q/2LA, insert the stylet wire into the tube through Luer-lock connector-1. Then mount the grip onto Luer-lock connector-1 and confirm that the stylet is securely attached.
3. Connect a sterile syringe filled with a contrast medium, medical fluid or saline solution to the injection port. Inject the fluid until the air inside the Tube is forced out.
4. Insert the distal end of the instrument into the target site.
5. Confirm that the stopcock is open (see Figure 4.1).
6. Mount the sterile syringe onto the air feeding port. Inject the specified amount of air into the instrument (see the tables in Section 2.2, "Specifications" to inflate the balloon).
7. Turn the knob on the stopcock 90° to close the stopcock.

8. Depress the sterile syringe's plunger to inject the fluid.

○ Retrieval

WARNING

- When retrieving a foreign object, do not operate the instrument abruptly or with excessive force. Doing so could cause patient injury, such as hemorrhages or mucous membrane damage. It could also burst the balloon or impede its deflation, which could cause the balloon catheter to become stuck inside the patient, or cause the distal end of the instrument to break off and remain inside the patient.
 - If the balloon becomes stuck, slowly withdraw it together with the endoscope and confirm that there is no bleeding. Forcibly withdrawing the instrument could cause its distal end to break off and remain inside the patient.
1. Insert the distal end of the instrument into the target site.
 2. Confirm that the stopcock is open (see Figure 4.1).
 3. Mount the sterile syringe onto the air feeding port. Inject the specified amount of air into the instrument (see the tables in Section 2.2, "Specifications" to inflate the balloon).
 4. Turn the knob on the stopcock 90° to close the stopcock.
 5. Pull the instrument to clear the foreign object.

○ Hemostasis

1. Insert the distal end of the instrument into the target site.
2. Confirm that the stopcock is open (see Figure 4.1).
3. Mount the sterile syringe onto the air feeding port. Inject the specified amount of air into the instrument (see the tables in Section 2.2, “Specifications” to inflate the balloon).
4. Turn the knob on the stopcock 90° to close the stopcock.

○ Changing the Patient’s Position (B5-2LA and B7-2LA Only)

WARNING

- Do not remove the endoscope from the body cavity quickly. Infectious substances attached to the endoscope such as blood or mucous may scatter, posing an infection control risk.
 - Hold the instrument when reinserting the endoscope. Otherwise, the instrument will move with the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
 - Do not withdraw the endoscope past the instrument’s Branch. If the endoscope is withdrawn further, the instrument will move with the endoscope. This may cause mucous membrane damage.
1. Leave the instrument inside the patient and completely withdraw the endoscope from the body cavity.

2. Change the patient's position.
3. Insert the endoscope into the body cavity again.

Withdrawing the Instrument From the Endoscope

WARNING

Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucous, or other patient debris and pose an infection control risk.

CAUTION

- Do not withdraw the instrument from the endoscope while the balloon is inflated. This could damage the endoscope and/or instrument.
 - Do not withdraw the instrument from the endoscope if the forceps elevator is up. This could damage the instrument.
1. Turn the knob on the stopcock back 90° to open the stopcock.
 2. Pull the sterile syringe's plunger to deflate the balloon.
 3. If the endoscope is equipped with a forceps elevator, lower the forceps elevator.
 4. Withdraw the instrument from the endoscope.

Disposal

WARNING

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.

- The instrument is a single-use, disposable item. Do not reuse or attempt to sterilize. Reusing the instrument could pose an infection control risk, cause tissue irritation or malfunction.

After using the instrument, dispose of it in an appropriate manner.



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— Manufactured by —



OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Fax: (042)646-2429 Telephone: (042)642-2111

— Distributed by —

OLYMPUS AMERICA INC.

3500 Corporate Parkway, P.O. Box 610 Center Valley, PA
18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS SURGICAL & INDUSTRIAL AMERICA INC.

One Corporate Drive, Orangeburg, N.Y. 10962, U.S.A.
Fax: (845)398-9444 Telephone: (845)398-9400

OLYMPUS LATIN AMERICA, INC.

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332



OLYMPUS MEDICAL SYSTEMS EUROPA GMBH

(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany Telephone: (040)237730



KEYMED LTD.

KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY

117071, Moscow, Malaya Kaluzhskaya 19, bld. 1, fl.2, Russia
Fax: (095)958-2277 Telephone: (095)958-2245

OLYMPUS (BEIJING) SALES & SERVICE CO.,LTD.

Room 1202, NCI Tower, A21 Jianguomenwai Avenue Chaoyang
District Beijing 100022 PRC
Fax: (10)6569-3545 Telephone: (10)6569-3535

OLYMPUS KOREA CO.,LTD.

8F, Hyundai Marines Bldg., 646-1, Yeoksam-Dong, Kangnam-Gu, Seoul 135-080 Korea
Fax: (02)6255-3499 Telephone: (02)1544-3200

OLYMPUS SINGAPORE PTE LTD.

491B, River Valley Road #12-01/04, Valley Point Office Tower, Singapore 248373
Fax: 6834-2438 Telephone: 6834-0010

OLYMPUS AUSTRALIA PTY. LTD.

31 Gilby Road, Mount Waverley, VIC., 3149, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

